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09/683,003	11/07/2001	Shiguang Yu	6601-00	5003

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/683,003	YU ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

In view of the Appeal Brief filed on 8/24/2006, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.


JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1200

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for treatment of poor hair growth or alopecia in sheep or treatment of poor hair growth or alopecia where the cause is selenium toxicity or hypothyroidism, does not reasonably provide enablement for at least assisting in preventing poor hair growth or alopecia in animals,

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including dogs, cats or sheep, or treatment of poor hair growth or alopecia over the entire scope of the limitation animals, including dogs and cats. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The claims are directed to at least assisting in preventing or treatment of poor hair growth or alopecia with about 0.5 to about 4.5 mg/Kg of selenium in animals, including dogs, cats or sheep.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record discloses that dietary supplementation of selenium in can increase wool production in sheep, that selenium toxicity in dogs, cats and sheep can result in hair loss or alopecia and that selenium should be provided in or reduced to levels which do not result in toxicity. The prior art of record also discloses that hypothyroidism can result in poor hair growth or alopecia and that selenium supplementation is effective in treating hypothyroidism. However, the prior art does not disclose that selenium supplementation in the amounts claimed can prevent poor hair growth or alopecia to the extent of the scope of the claimed invention. The limitation "at least assisting in preventing" poor hair growth or alopecia is not defined by the Specification and claims as originally filed. However, said limitation includes within its scope "prevention" of poor hair growth or alopecia. As such, predictability in the art is low with respect to prevention of poor hair growth or alopecia to the extent of the scope of the claimed invention and treatment of poor hair growth or alopecia other than in wool production of sheep, selenium toxicity or hypothyroidism resulting from selenium deficiency.

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The amount of direction or guidance present and the presence or absence of working examples:

The Specification provides one example in which hair is shaved from different areas on dogs and the rate of hair growth is measured over time in relation to the amount of selenium (provided as selenomethionine) provided in a diet which is nutritionally balanced and complete for an adult dog except for selenium (Specification, paragraphs 0010-0015). As such, the hair and hair follicle is still present. Alopecia, on the other hand, is the absence or loss of hair. See Stedman's Medical Dictionary (27th ed. 2000) (printed from <http://www.thomsonhc.com/pdrel/librarian/PFDDefaultActionId/pdrcommon.Stedmans> on 11/2/2006). Since the example does not show that selenium administration result in new hair growth, the example does not provide evidence that administration of selenium will at least assist in the prevention of alopecia. The test showed hair growth of cut hair at each amount tested although at certain amounts (0.034, 0.085, 5.045 mg/kg dietary Se) there was decreased hair growth at week 11 and week 22 compared to other amounts (0.123, 0.527, 1.025 mg/kg dietary Se (Paragraph 0015, Table 1). However, there was no testing of a control hair growth or indication as to what amount of growth was given or amount of hair growth that would constitute poor hair growth, as such, there is no showing that selenium would at least assist in preventing poor hair growth. The Specification does not disclose what other agents or compounds would be required in order for selenium to assist in prevention of poor hair growth or alopecia. Finally, in an article in which the inventors were the named authors, the article indicated that the daily hair growth for beagle dogs is 0.34-0.40 mm (Yu et al., Page 150). This is higher than any of the daily hair growth rate data set forth in Table 1 of the Specification. As such, the only example provided actually provides evidence

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the claimed range is not effective to at least assist in preventing or to even treat poor hair growth or alopecia in all animals, especially dogs.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim at least assisting in preventing or treatment poor hair growth or alopecia without out limitation as to the cause of the poor hair growth or alopecia. The limitation "at least assisting in preventing" is not defined by the Specification and no base line is provided for what would constitute poor hair growth in dogs, cats, sheep or other animals. The Specification and claims as originally filed only recited "preventing or treating". In any case, the phrase "at least assisting in preventing" includes within its scope 100% prevention of poor hair growth or alopecia or prevention over the lifetime of the animal. The evidence submitted and the prior art of record does not provide evidence that is commensurate in scope with the claimed invention. The example in the Specification sets forth hair growth rates in beagles in amounts falling within the claimed range of selenium that are below the daily hair growth rate in beagles. The prior art discloses or suggests providing amounts of dietary selenium in or reducing amounts of dietary selenium to levels which are not toxic as selenium toxicity can cause poor hair growth or alopecia. The prior art suggests that wool production in sheep can be increased by selenium supplementation. The prior art discloses that selenium supplementation can treat hypothyroidism and that hypothyroidism can cause poor hair growth or alopecia. However, the prior art does not disclose that selenium can provided 100% prevention of poor hair growth or that dietary selenium at the levels claimed is generally effective in treating poor hair growth or alopecia what ever the cause and in any animal. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine that

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administration of selenium will at least assist in preventing poor hair growth or alopecia over the entire scope of the claimed invention, determine which other compounds or agents would allow selenium to assist in the prevention of poor hair growth or alopecia and what amounts within the claimed range would be effective in treating poor hair growth or alopecia in a given animal species that is not the result of selenium toxicity or hypothyroidism which is treatable by selenium supplementation..

The examiner has duly considered the Applicant's arguments but deems them moot in light of the new scope of enablement rejection above.

Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "at least assisting in preventing poor hair growth or alopecia". The Specification and claims as originally filed only recited "preventing or treating" poor hair growth or alopecia. The phrase "at least assisting in preventing poor hair growth or alopecia" encompasses or implies embodiments in which there is some other unidentified agent or compound or mixtures of the same that must be administered with selenium in order to prevent poor hair growth or alopecia. However, the specification and claims as originally filed only disclose that selenium is used to prevent or treat poor hair growth or alopecia and does not disclose that selenium assists in preventing poor hair growth or alopecia with some other agent or compounds or mixtures of said other agent or compound. As such, there is no indication from the specification and claims as originally filed that would reasonably convey to one of ordinary

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skill in the art that the inventors deemed “assisting in preventing poor hair growth or alopecia” to be part of their invention. See, e.g., PIN /NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1248, 64 USPQ2d 1344, 1353 (Fed. Cir. 2002) (Claim for a method of inhibiting sprout growth on tubers by treating them with spaced, sequential application of two chemicals was held invalid for lack of adequate written description where the specification indicated that invention was a method of applying a “composition,” or mixture, of the two chemicals.) In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) (“If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.”).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2-4 are rejected under 35 U.S.C. 102(b) as being anticipated by NAC, Nutrient Requirements of Sheep (6th Revised Ed. 1985) (hereinafter NAC-NRS).

NAC-NRS expressly discloses feeding of 2 ppm or mg/kg of diet dry matter of selenium and that chronic selenium toxicity occurs when sheep consume over a prolonged period of time seleniferous plants containing more than 3 ppm of selenium and that signs of said toxicity include loss of wool (Page 22, Page 50, Table 7).

Claim 2 is directed to a method for controlling the rate of hair growth in a dog, cat or sheep comprising feeding the dog, cat or sheep from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis. The term "controlling" encompasses reducing, maintaining or increasing the rate of hair growth. Since the claim does not indicate whether the rate of hair growth is reduced, maintained or increased, the prior art process inherently reads on the claimed method as the amount administered to the sheep fall within the claimed range of selenium of claim 2. Claims 3 and 4 claim the same amounts except that the claimed method encompasses at least assisting in preventing poor hair growth or alopecia in animals and dogs, cats or sheep, respectively. As such, claims 3 and 4 do not require that the sheep actually have or be disclosed to have poor hair growth or alopecia. Since the prior art method discloses feeding of 2 mg/kg of diet dry matter of selenium to sheep and said amount falls within the scope of the claimed range, the prior art method reads on the invention claimed in claims 3 and 4.

Claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Vleet.

Van Vleet expressly discloses supplementing the diet of dogs that was deficient in vitamin E and selenium with 0.5 ppm Se and 1.0 ppm Se as sodium selenite (Pages 769, 770).

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Claim 2 is directed to a method for controlling the rate of hair growth in a dog, cat or sheep comprising feeding the dog, cat or sheep from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis. The term "controlling" encompasses reducing, maintaining or increasing the rate of hair growth. Since the claim does not indicate whether the rate of hair growth is reduced, maintained or increased, the prior art process inherently reads on the claimed method as the amounts administered to the dogs fall within the claimed range of selenium of claim 2. Claims 3-5 claim the same amounts except that the claimed method encompasses at least assisting in preventing poor hair growth or alopecia in animals, dogs, cats or sheep, and dog and cats, respectively. As such, the claim does not require that the dog actually have or be disclosed to have poor hair growth or alopecia. Since the prior art method discloses feeding of 0.5 ppm and 1 ppm of Se to dogs and said amount falls within the scope of the claimed range, the prior art method reads on the invention claimed in claims 3-5.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over NAC-NRS.

NAC-NRS discloses feeding of 0.1-0.2 to a maximum of 2 ppm or mg/kg of diet dry matter of selenium to meet the nutritional requirements of sheep and that chronic selenium toxicity occurs when sheep consume over a prolonged period of time seleniferous plants containing more than 3 ppm of selenium and that signs of said toxicity include loss of wool (Page 22, Page 50, Table 7).

The prior art discloses feeding of 0.1-0.2 to a maximum of 2 mg/kg of diet dry matter of selenium and that chronic selenium toxicity occurs when sheep consume over a prolonged period of time seleniferous plants containing more than 3 ppm of selenium and that signs of said toxicity include loss of wool. The difference between the prior art and the claimed invention is

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that the prior art does not expressly disclose treatment of poor hair growth or alopecia in sheep. However, the prior art amply suggests the same as the prior art discloses that chronic selenium toxicity occurs when sheep consume over a prolonged period of time seleniferous plants containing more than 3 ppm of selenium and that signs of said toxicity include loss of wool. As such, it would have been well within the skill of and one of ordinary skill in the art treat loss of wool due to selenium toxicity by reducing the amount of dietary selenium to a range of 0.1-0.2 to a maximum of 2 mg/kg of diet dry matter of selenium with the expectation that said range would meet the nutritional requirements of sheep.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over NAC, Nutrient Requirements of Cats (1986) (hereinafter "NAC-NRC") in view of Dey et al..

NAC-NRC discloses that selenium deficiency in cats has not been observed, although it would appear likely from work with other species that a specific dietary requirement does exist (Pg. 19). It is disclosed that levels of selenium in excess of 5 mg/kg are toxic for many animal species but have not been reported to be toxic to the cat (Pg. 19). It is disclosed that based on the requirement of selenium in other species, a minimum requirement of 100 micrograms Se/kg diet is recommended (Pg. 19).

Dey et al. disclose that known toxic effects of selenium, such brittleness of hair and loss of long hair were observed in several individuals of the four animal species studied, flying squirrel, leopard cat, civit cat and leopard (Pages 1,8).

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The prior art discloses feeding of a minimum of 100 microgram Se/kg diet to cats and that selenium levels in excess of 5 mg/kg have been reported to be toxic in other animal species. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose treatment of poor hair growth or alopecia in cats. However, the prior art amply suggests the same as the prior art discloses that a minimum requirement of 100 micrograms Se/kg diet is recommended, that a level in excess of 5 mg/kg of diet has been reported to be toxic in other species of animal, and that selenium toxicity in leopards, leopard cats and civet cats has resulted in brittle hair and loss of long hair. As such, it would have been well within the skill of and one of ordinary skill in the art to restrict the amount of selenium in the diet to less than 5 mg/kg of diet to a minimum of 100 micrograms/kg of diet with the expectation that said amount would meet the selenium nutritional requirements of the cat while treating or reducing the risk of poor hair growth or alopecia due to selenium toxicity.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arthur et al in view of Awadeh et al., Ahsan et al., Messenger, Daminet et al., NAC-NRS, NAC, Nutrient Requirements of Dogs (1985) (hereinafter NAC-NRD) and NAC-NRC.

Arthur et al. disclose that selenium deficiency impairs thyroid hormone metabolism by inhibiting the synthesis and activity of the iodothyronine deiodinases that convert thyroxine to the more metabolically active triiodothyronine (T3) (Page 37, Abstract).

Awadeh et al. disclose that selenium supplementation increased T3 levels in cows, guinea pigs and calves and that selenium deficient rats had reduced T3 concentrations in plasma (page 1208).

Ahsan et al. disclose that T3 regulates growth, differentiation and development of various tissues and that hypothyroidism leads to dry, course and brittle hairs that become increasingly thinner and that spare scalp hair, loss of the outer third of eyebrows and diminished body hair are often seen in hypothyroidism (page 179). It is disclosed that administration of T3 stimulates the proliferation and/or metabolism of outer root sheath cells and dermal papilla cells (Page 179, Abstract).

Messenger discloses that thyroxine, which is converted to the active hormone triiodothyronine, increased hair length in rats and hair growth in sheep and badgers (pg. 633).

Daminet et al. disclose that alopecia is a common clinical sign of hypothyroidism (pg. 699).

NAC-NRS disclose feeding a maximum of 2 ppm or mg/kg of diet dry matter of selenium and that chronic selenium toxicity occurs when sheep consume over a prolonged period of time seleniferous plants containing more than 3 ppm of selenium and that signs of said toxicity include loss of wool (Page 22, Page 50, Table 7). It is disclosed that the minimum requirement of selenium in sheep is 0.1-0.2 mg/kg diet dry matter (Page 50, Table 7).

NAC-NRD discloses that dogs fed a purified, Torula yeast-based diet that was deficient in selenium over a period of 40 to 60 days exhibited clinical signs of deficiency whereas dogs fed diets supplemented with 0.5 mg and 1.0 mg/kg selenium did not develop clinical signs of deficiency (page 21). It is disclosed that the required minimum concentration of selenium in dog

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food formulated for growth is 0.11 mg/kg dry basis (3.67 kcal ME/g) (Page 44, Table 2). It is disclosed that the minimum selenium requirement of dogs for growth and maintenance (amounts per kg of body weight per day (average 30kg BW growing beagle puppy consuming 600 kcal ME/day, average 10-kg-BW adult dog consuming 742 kcal ME/day) is 6.0 and 2.2 micrograms, respectively (Page 44, Table 1).

NAC-NRC discloses that selenium deficiency in cats has not been observed, although it would appear likely from work with other species that a specific dietary requirement does exist (Pg. 19). It is disclosed that levels of selenium in excess of 5 mg/kg are toxic for many animal species but have not been reported to be toxic to the cat (Pg. 19). It is disclosed that based on the requirement of selenium in other species, a minimum requirement of 100 micrograms Se/kg diet is recommended (Pg. 19).

The prior art discloses that disclose that selenium deficiency impairs thyroid hormone metabolism by inhibiting the synthesis and activity of the iodothyronine deiodinases, which convert thyroxine to the more metabolically active triiodothyronine (T3). The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method for controlling the rate of hair growth or treating poor hair growth or alopecia in a dog or cat with about 0.5 to about 4.5 selenium mg/kg. However, the prior art amply suggests the same as the prior art discloses that selenium deficiency impairs thyroid hormone metabolism and conversion to T3, that selenium deficiency results in T3 deficiency, that T3 stimulates hair cell growth and/or metabolism, that administration of thyroxine, which is converted to T3 by an enzyme which requires selenium, is effective in growing hair in rats, sheep and badgers and that alopecia is a symptom of hypothyroidism. The prior art discloses the selenium requirements for

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dogs, cats and sheep, which amounts fall within or overlap the claimed range of about 0.5-4.5 mg/kg diet dry matter. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to administer similar amounts of selenium to dogs or cats with the expectation that selenium administration would control the rate of hair growth or treat poor hair growth or alopecia in animals in which poor hair growth or alopecia is due to hypothyroidism that is caused by selenium deficiency and treatable by selenium supplementation and to use levels of selenium below 5 mg/kg diet dry matter in order to reduce the risk of selenium toxicity.

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein. To the extent that the Applicant's arguments may be applicable the following applies:

The Applicant refers to the Specification at page 1, lines 19-26 and argues that the animals are not selenium deficient animals. However, the Specification at page 1, lines 19-26 does not state that the animals are not selenium deficient. Further, in the working example, the beagles tested were fed a basal diet that was deficient in selenium (Specification, paragraph 0012). In any case, the claims are not limited to animals that are not deficient in selenium. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant has not provided evidence that there is no known correlation between selenium between alopecia and selenium. The arguments of counsel cannot take the place of evidence in the record. In *re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In

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re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) (“An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.”). Further, the claims are not limited to treatment of alopecia but encompass treatment of poor hair growth. Further, claim 2 is not limited to treatment of alopecia or poor hair growth but encompasses increasing, maintaining or reducing the rate of hair growth in dogs, cats and sheep. In any case, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

In this case, the prior art discloses that hypothyroidism can be caused by selenium deficiency, that supplementation with selenium is effective in treating hypothyroidism and alopecia or poor hair growth is a symptom of hypothyroidism. As such, one of ordinary skill in the art would expect that where the alopecia or poor hair growth is due to hypothyroidism resulting from selenium deficiency that supplementation with selenium would be effective in treating the alopecia or poor hair growth. As indicated above, the claims are not limited to

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treatment of alopecia, much less treatment of alopecia in which the animals are not selenium deficient.

The Applicant makes various arguments with respect to WO 98/11122, however, said reference is no longer a part of the rejection herein. The Applicant argues that there is nothing in Arthur to motivate a skilled artisan to conclude that this reference can be combined with the other references to achieve an invention directed to alopecia. However, as indicated above the claims are not limited to alopecia and there does not have to be an express motivation in the art in order for the references to be combined. Further, the claims are not limited to animals that are not selenium deficient, the example in the Specification used a basal diet that was deficient in selenium and the combined teachings of the references disclose amounts of selenium that fall within or overlap the claimed range of selenium (the Lee et al., Shields et al., Hayek et al. and WO 98/11122 references cited by the Applicant are no longer part of the rejection herein). The Applicant argues that dogs fed diets containing amounts of selenium inside the claimed range had higher rates of hair growth than dogs fed diets containing amounts of selenium outside of the claimed range. This is not accurate as beagles fed 0.123 mg of Se/kg of diet has similar rates of hair growth as beagles fed 0.527 mg/kg and 1.025 mg/kg (Specification, Paragraph 0015, Table 1). Further, notwithstanding the same, as indicated above, none of the amounts tested exhibited a rate of hair growth that was at least the same as that reported to be the average rate of hair growth for beagles. Since the Applicant's only example in the Specification failed to provide a rate of hair growth that at least meets the average rate of hair growth in beagles and does not provided evidence of new hair growth, said example fails to support the criticality of the claimed range for poor hair growth or alopecia in claims 3-5. With respect to claim 2, claim 2 only

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requires control of hair growth and thus is not limited to increasing the rate of hair growth but also encompasses reduction and maintenance of the rate of hair growth. As such, any amount in the prior art would “control” the rate of hair growth and the example fails to support the criticality of the claimed range.

The Applicant argues that the claimed amounts are added to a normal nutritional diet that is not deficient in selenium. However, the claims do not indicate the same and the example in the Specification refutes said assertion. The basal diet in said example, as indicated above, was deficient in selenium. Further, the claims do not exclude the presence of other compounds and the amount of selenium is based on the weight of the diet. As such, the claims if not actually requiring that selenium be added to the diet at least encompass embodiments in which selenium is added to the diet and thus selenium would be combined with other compounds.

In conclusion, the Applicant’s argued differences between the prior art and the claimed invention are not supported by the prior art or the Specification and claims as follows:

(1) the claims do not indicate that the animals are fed a diet that is not selenium deficient and the example in the Specification administered a basal diet that was deficient in selenium;

(2) the claims do not exclude the addition of other compounds and at most actually require that other compounds be present, i.e. the diet, and the prior art do not require the addition of other compounds in order for selenium to be effective;

(3) the amounts of selenium disclosed in the prior art fall within and/or suggest ranges that fall within or overlap the claimed range and the criticality of the claimed range has not been established; and

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(4) overcoming health problems caused by selenium deficiency in the prior art include treatment of poor hair growth or alopecia and are not excluded by the claims.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

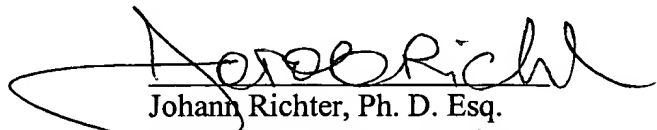
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

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